AMENDMENTS

In the Claims:

1. (Currently amended) A thermal adhesion granulation process for preparing direct tabletting formulations or aids, comprising the step of subjecting all or part of a mixture comprising:

(a) from about 5 to about 99 % by weight of one or more diluent excipients and/or from 0 to about 99% by weight of a pharmaceutically-active ingredient;

(b) from about 1 to about 95 % by weight of a binder excipient; and optionally with,

(c) from 0 to about 10% by weight of a disintegrant excipient;

to heating at a temperature range of from about 30 to about 130°C under the condition of from about 0.1 to about 20% initial moisture content and/or from about 0.1 to about 20% initial content of a pharmaceutically-acceptable organic solvent in a closed system ~~under~~ with mixing by tumble rotation until ~~the formation of~~ granules form.

2. A process as defined in claim 1, wherein the temperature range is from about 40 to about 110°C.

3. A process as defined in claim 1, wherein the temperature range is from about 60 to about 105°C.

4. A process as defined in claim 1, wherein the initial moisture content is from about 2 to about 15%.

5. A process as defined in claim 1, wherein the initial moisture content is from about 4 to about 10%.

6. A process as defined in claim 1, wherein the initial organic solvent content is from about 0.1 to about 10%.

7. A process as defined in claim 1, where the initial organic solvent content is from about. 0.5 to about 5%.

8. A process as defined in claim 1, wherein the diluent excipient is powdered cellulose, microcrystalline cellulose, lactose, starch, or dibasic calcium phosphate.

9. A process as defined in claim 1, wherein the pharmaceutically-active ingredient is acetaminophen or ascorbic acid.

10. A process as defined in claim 1, wherein the binder excipient is soluble polyvinyl pyrrolidone or hydroxypropylcellulose.

11. A process as defined in claim 1, wherein the disintegrant excipient is crospovidone, sodium starch glycolate, reticulated carboxymethylcellulose, or low-substituted hydroxypropylcellulose.

12. A process as defined in claim 1, wherein the diluent excipient is microcrystalline cellulose.

13. (Currently amended) A process as defined in claim 12, wherein ~~the microcrystalline cellulose is of a type in which~~ about 90% of the microcrystalline cellulose particles are in the particle size range from about 1 μm to about 125 μm, and the average particle size of the microcrystalline cellulose particles is from about 10 μm to about 70 μm.

14. A process as defined in claim 1, wherein the binder excipient is soluble polyvinyl pyrrolidone.

15. A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K value of from about 12 to about 120.

16. A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K value of from about 20 to about 95.

17. A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K value of from about 25 to about 35.

18. (Currently amended) A process as defined in claim 1, wherein the binder excipient further contains from 0 to about 10% ~~(~~by weight with respect to the binder~~)~~ of an anticaking agent.

19. (Currently amended) A process as defined in claim 18, wherein the binder excipient contains from about 0.01 to about 10% ~~(~~by weight with respect to the binder~~)~~ of an anticaking agent.

20. ~~(Currently amended)~~ A process as ~~defined~~ in claim 18, wherein the binder excipient contains from about 2 to about 4% ~~(~~by weight with respect to the binder~~)~~ of an anticaking agent.

21. A process as defined in claim 18, wherein the anticaking agent is dibasic calcium phosphate anhydrous.

22. (Currently amended) A product of ~~thermal adhesion granulation~~ the process of claim 1 ~~for preparing direct tabletting formulations or aids as defined in claim 1~~.

23. (Currently amended) A powder mixture of soluble polyvinyl pyrrolidone containing from about 0.01 to about 10% ~~(~~by weight with respect to the polyvinyl pyrrolidone~~)~~ of dibasic calcium phosphate anhydrous.

24. A direct tabletting formulation or aid comprising:

i) from about 5 to about 99% by weight of powder cellulose, microcrystalline cellulose, lactose, starch, or dibasic calcium phosphate;

ii) from 0 to about 99% by weight of acetaminophen or ascorbic acid;

iii) from about 1 to about 95% by weight of a soluble polyvinyl pyrrolidone which contains from about 0.01 to about 10% (by weight with respect to the polyvinyl pyrrolidone) of dibasic calcium phosphate anhydrous; and

iv) from 0 to about 10% by weight of crospovidone, sodium starch glycolate, reticulated carboxymethylcellulose, or low-substituted hydroxypropylcellulose.

25. (Previously added) A tablet which comprises a product as defined in claim 22.

26. (Previously added) A tablet which comprises the powder mixture as defined in claim 23.

27. (Previously added) A tablet which comprises a tabletting formulation or aid as defined in claim 24.

28. (Previously added) A capsule which comprises a product as defined in claim 22.

29. (Previously added) A capsule which comprises a powder mixture as defined in claim 23.

30. (Previously added) A capsule which comprises a tabletting formulation or aid as defined in claim 24.

31. (Previously added) A pellet which comprises a product as defined in claim 22.

32. (Previously added) A pellet which comprises a powder mixture as defined in claim 23.

33. (Previously added) A pellet which comprises a tabletting formulation or aid as defined in claim 24.

34. (New) A thermal adhesion granulation process, which comprises:

dry-blending binder excipient, one or more diluent excipients, and a pharmaceutically-active ingredient;

adding water and/or a pharmaceutically-acceptable organic solvent to the dry-blended mixture; and

heating at a temperature range from about 30°C to about 130°C with mixing in a closed system until granules form, wherein:

the binder excipient is from about 1% to about 95% by weight,

the one or more diluent excipients are from about 5% to about 99% by weight,

the pharmaceutically-active ingredient is from 0% to about 99% by weight, and

the water and/or the pharmaceutically-acceptable organic solvent is from about 0.1% to about 20% content before heating.

35. (New) The process of claim 34, wherein the mixing is by tumble rotation.

36. (New) A process as defined in claim 34, wherein the temperature range is from about 40 to about 110°C.

37. (New) A process as defined in claim 34, wherein the temperature range is from about 60 to about 105°C.

38. (New) A process as defined in claim 34, wherein the initial moisture content is from about 2 to about 15%.

39. (New) A process as defined in claim 34, wherein the initial moisture content is from about 4 to about 10%.

40. (New) A process as defined in claim 34, wherein the initial organic solvent content is from about 0.1 to about 10%.

41. (New) A process as defined in claim 34, where the initial organic solvent content is from about 0.5 to about 5%.

42. (New) A process as defined in claim 34, wherein the diluent excipient is powdered cellulose, microcrystalline cellulose, lactose, starch, or dibasic calcium phosphate.

43. (New) A process as defined in claim 34, wherein the pharmaceutically-active ingredient is acetaminophen or ascorbic acid.

44. (New) A process as defined in claim 34, wherein the binder excipient is soluble polyvinyl pyrrolidone or hydroxypropylcellulose.

45. (New) The process of claim 34, wherein a disintegrant excipient is included in the dry-blending step. essen. cl. 11

46. (New) A process as defined in claim 45, wherein the disintegrant excipient is crospovidone, sodium starch glycolate, reticulated carboxymethylcellulose, or low-substituted hydroxypropylcellulose.

47. (New) A process as defined in claim 34, wherein the diluent excipient is microcrystalline cellulose.

48. (New) A process as defined in claim 47, wherein about 90% of the microcrystalline cellulose particles are in the range from about 1 μm to about 125 μm, and the average particle size of the microcrystalline cellulose particles is from about 10 μm to about 70 μm.

49. (New) A process as defined in claim 34, wherein the binder excipient is soluble polyvinyl pyrrolidone.

50. (New) A process as defined in claim 49, wherein the soluble polyvinyl pyrrolidone has a K value of from about 12 to about 120.

51. (New) A process as defined in claim 49, wherein the soluble polyvinyl pyrrolidone has a K value of from about 20 to about 95.

52. (New) A process as defined in claim 49, wherein the soluble polyvinyl pyrrolidone has a K value of from about 25 to about 35.

53. (New) A process as defined in claim 34, wherein the binder excipient further contains from 0 to about 10% by weight with respect to the binder of an anticaking agent.

54. (New) A process as defined in claim 53, wherein the binder excipient contains from about 0.01 to about 10% by weight with respect to the binder of an anticaking agent.

55. (New) A process as defined in claim 53, wherein the binder excipient contains from about 2 to about 4% by weight with respect to the binder of an anticaking agent.

56. (New) A product prepared by the process of claim 34.

57. (New) A tablet comprising the product of claim 56.

58. (New) A capsule comprising the product of claim 56.

59. (New) A pellet comprising the product of claim 56.

60. (New) The process of claim 1, wherein the mixing is by tumble rotation.

61. (New) A method of making a powder mixture comprising polyvinyl pyrrolidone, which comprises mixing with the composition dibasic calcium phosphate anhydrous in an amount of about 0.01% to about 10% by weight with respect to the polyvinyl pyrrolidone.